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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,046	09/27/1999	THOMAS MEADE	A-58634-6/RF	9059

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/405,046	MEADE ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2002 and 18 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,16,17 and 22-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,16,17,22,23,30 and 32* is/are rejected.

7)☒ Claim(s) *24-29,31 and 33-41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16 & 20* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the following:

a. Paper No. 18, filed 6/18/02, wherein an acceptable RCE was filed; and

b. Paper No. 19, filed 6/18/02, wherein claims 12, 16, 22, and 23 were amended and claims 24-41 were added.

Note: Claims 12, 16, 17, and 22-41 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments filed 6/18/02 (Paper No. 19) to the rejection of claims 12, 16, 17, 22, and 23 made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed non-persuasive for the reasons set forth below.

Double Patenting Rejections

The rejection of claims 12, 16, 17, 22, and 23 under the judicially created doctrine of obviousness-type double patenting under US Patent Nos. 5,707,605 and 5,980,862 is MAINTAINED for reasons of record in the Office Action mailed 5/11/01, Paper No. 11.

Note: It is duly noted that Applicant requests that the obviousness-type double patenting rejection be held in abeyance until the claims are indicated as allowable at which time Applicant intends to file a terminal disclaimer.

103 Rejections

The rejection of claims 12, 16, and 17 under 35 USC 103(a) as being unpatentable over Garlich et al (US Patent No. 5,133,956) in view of Watson (US Patent No. 5,914,095) is MAINTAINED for the reasons set forth in the Office Action mailed 5/11/01, Paper No. 11, and those found below.

Applicant asserts that the composition of Garlich et al and Watson et al are not activatible MRI agents and the references neither teach nor disclose a method of turning an MRI agent off by hindering the rapid exchange of water.

In response to Applicant's arguments, the following response is given. First, in regards to the references not teaching activatible agents, since the cited prior art agent comprises the same components as Applicant's invention, it would be obvious to a skilled practitioner in the art that Garlich et al in combination with Watson et al, in addition to Applicant's invention, would all possess the same characteristics; hence, if one group of compositions are activatible, then they all would be expected to be activatible. Furthermore, Applicant is arguing a limitation that is not considered in determining patentability of the claim. Specifically, claims 12, 16, 17, 22-29 are compound/composition claims. Thus, the intended use of the agent, activating the agent to hinder the rapid exchange of water, is not given patentable weight. Applicant is reminded that the intended use of a compound/composition is given patentable weight in method claims, not compound/composition claims. Likewise, Applicant's assertion that the agent of the instant invention detects the presence of a targeting substance is not given patentable weight because patentability of compound/composition claims is

dependent upon the components present in the compound/composition, not on the utility of the compound/composition.

Secondly, Applicant assets that there is no motivation in the cited prior art to modify or combine the references. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Garlich et al and Watson et al are directed to diagnostic/therapeutic agents comprising a DOTA chelator that may be conjugated to a site directed macromolecule such as a protein or peptide.

NEW GROUNDS OF REJECTIONS

112 Rejections

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 30, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12, 30, and 32: The claims as written are ambiguous because it is unclear what is attached to the COO- groups. Did Applicant intend to attach hydrogen atoms? Please make the appropriate change(s) and point to page and line numbers for support of such changes.

CLAIM OBJECTIONS

4. Claims 24-29, 31, and 33-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the additional claim limitations present in the dependent claims. The closest prior art is Applicant's own work which is cited in the double patenting rejections above.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

August 19, 2002